UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MDL NO. 13-02419-RWZ

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION

MEMORANDUM OF DECISION

August 29, 2014

ZOBEL, D.J.

This multidistrict litigation stems from an outbreak of fungal meningitis caused by contaminated methylprednisolone acetate ("MPA") manufactured and sold by the New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"). Before the court now are several motions to dismiss under Fed. R. Civ P. 12(b)(6), filed by clinic-related defendants from Tennessee and New Jersey, based on alleged noncompliance with certain state law requirements and failure to state a claim on which relief can be granted.

## I. Background[1]

### A. Factual and Procedural History

NECC operated a compounding pharmacy in Framingham, Massachusetts, that combined and mixed ingredients to create specific formulations of pharmaceutical products. In fall 2012, health officials traced a number of cases of fungal meningitis to

[1] A detailed account of the background of the case is set forth in previous opinions of the court. See, e.g., In re New England Compounding Pharm., Inc. Prods. Liability Litig., 496 B.R. 256, 260-263 (D. Mass. 2013). Only a brief summary is set forth here.

injections in and around the patients' spinal cords of MPA that had been manufactured by NECC. NECC initiated a recall of several contaminated batches of MPA before eventually surrendering its pharmacy license and ceasing production of all pharmaceutical products. NECC filed for Chapter 11 bankruptcy in December 2012.

Lawsuits alleging death or injury based on contaminated MPA were filed against NECC, affiliated entities and individuals, and/or health care providers in multiple state and federal jurisdictions around the country beginning in November 2012. In February 2013, the Judicial Panel on Multidistrict Litigation ("JPML") issued an order under 28 U.S.C. § 1407 transferring various federal court matters to this court for coordinated and consolidated pretrial proceedings; subsequent JPML orders also transferred "tag-along" cases. Other cases pending in both federal and state court were likewise transferred to this court via additional transfer orders. See In re New England Compounding Pharm., Inc. Prods. Liability Litig., 496 B.R. 256 (D. Mass. 2013) (Docket # 176); In re New England Compounding Pharm., Inc. Prods. Liability Litig., Civil Action No. 13-02419-RWZ, 2014 WL 2040139 (D. Mass. May 15, 2014) (Docket # 1131); June 4, 2014, Transfer Order (Docket # 1173).

On November 5, 2013, in accordance with MDL Order No. 6 (Docket # 209), the court-appointed plaintiffs' steering committee filed a master complaint against numerous non-NECC parties, including hospitals, clinics, and health care facilities (as well as their physicians, staff, agents, and employees), that allegedly obtained

contaminated MPA from NECC and administered it to their patients.[2] See Master Complaint ("Master Compl."), Docket # 545. Plaintiffs who already had cases on file or who wished to file in the multidistrict litigation thereafter submitted short-form complaints to assert facts and claims set out in the master complaint. A substantial number of short-form complaints name "clinic-related defendants" from Tennessee and New Jersey, several of whom filed the motions at bar.

### B. The Movants

As set forth in the parties' memoranda, the movants are aligned in the following groups:

#### 1. The Tennessee Clinic Defendants

Defendant St. Thomas Outpatient Neurosurgical Center, LLC ("STOPNC") is a licensed ambulatory surgery center located in Nashville, Tennessee. STOPNC purchased contaminated MPA from NECC and administered it to patients. Defendant Howell Allen Clinic, P.C. ("Howell Allen"), a neurosurgical group in Nashville, owns a 50% interest in STOPNC and staffs STOPNC pursuant to a management contract. Defendant John W. Culclasure, M.D., is an employee of Howell Allen and the medical director of STOPNC. Dr. Culclasure participated in the decision to purchase MPA from NECC for use at STOPNC and performed epidural steroid injections using that MPA. Defendant Debra V. Schamberg, R.N., an employee of Howell Allen and the facility director of STOPNC, also participated in the decision to purchase MPA from NECC for

[2] The master complaint was intended to be an administrative tool, allowing the allegations and claims against all defendants to be stated in one document.

use at STOPNC. STOPNC, Howell Allen, Dr. Culclasure, and Ms. Schamberg have been named, in various combinations, in suits filed by or on behalf of 117 patients.

Defendant Specialty Surgery Center, Crossville, PLLC ("SSC") is a licensed ambulatory surgery center in Crossville, Tennessee, that purchased contaminated MPA from NECC. Defendant Kenneth R. Lister, M.D., the owner of SSC, participated in the decision to purchase MPA from NECC for use at SSC and performed epidural steroid injections using that MPA. Dr. Lister is the sole owner and employee of his practice, defendant Kenneth Lister M.D., P.C. SSC is a defendant in suits filed by or on behalf of 24 patients; Dr. Lister is named in 11 of those actions, and his practice is named in five.

**2. The Saint Thomas Entities (Tennessee)**

The Saint Thomas Entities are comprised of defendants Saint Thomas West Hospital (formerly known as St. Thomas Hospital), Saint Thomas Network, and Saint Thomas Health. Saint Thomas Health owns both Saint Thomas West Hospital and Saint Thomas Network, which in turn is a co-owner of STOPNC with Howell Allen. The Saint Thomas Entities are named in vicarious liability claims in dozens of short-form complaints based on their alleged relationship with STOPNC.

**3. The Ascension Parties (Tennessee)**

The Ascension Parties are defendants Ascension Health Alliance and Ascension Health, which owns Saint Thomas Health. Some plaintiffs with claims against the Saint Thomas Entities have also asserted vicarious liability claims against the Ascension Parties.

#### 4. The Premier Defendants (New Jersey)

Defendant Premier Orthopaedic Associates and Sports Medicine Associates of New Jersey, LLC (trading as Premier Orthopaedic Associates) is an orthopedic practice located in Vineland, New Jersey, whose providers performed epidural injections of contaminated MPA obtained from NECC. Most of the injections were administered at defendant Premier Orthopaedic Associates Surgical Center, LLC, and were performed by defendant Kimberley Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D. The Premier Defendants have been named in ten actions.

### C. The Motions to Dismiss

The motions to dismiss fall into two categories. The first, brought by the defendants from Tennessee (Docket ## 770 and 779), seeks dismissal for plaintiffs' alleged failure to comply with the Tennessee Health Care Liability Act ("THCLA"). The second set of motions focuses on "global claims," i.e., claims against defendants alleged in all or a substantial number of cases. Each group of the above defendants has filed a separate "global claims" motion: the Tennessee Clinic Defendants (Docket # 771), the Saint Thomas Entities (Docket # 893), the Ascension Parties (Docket # 895), and the Premier Defendants (Docket # 831).

The motions will be addressed seriatim by category.

## II. Legal Standard

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550

U.S. 544, 570 (2007). Plausibility "is not akin to a probability requirement, but [requires] more than a sheer possibility that a defendant has acted unlawfully." Iqbal, 556 U.S. at 678. Thus, "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Id. When ruling on a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the court accepts as true all factual allegations contained in the complaint, but not legal conclusions. Id.

## III. Discussion

### A. Motions to Dismiss for Failure to Comply with the Tennessee Health Care Liability Act (Docket ## 770 and 779)

The Tennessee Clinic Defendants, Saint Thomas Entities, and Ascension Parties assert that plaintiffs have failed to comply with the Tennessee Health Care Liability Act ("THCLA"), Tenn. Code Ann. § 29-26-101, et seq., which establishes mandatory requirements that a Tennessee plaintiff must meet prior to filing a health care liability action, including giving pre-suit written notice and filing a certificate of good faith. Defendants argue that deficiencies cannot be cured by amendment and that noncompliance warrants dismissal.

Plaintiffs counter that the THCLA does not apply to any original complaints that brought only claims for products liability against defendants. Plaintiffs later amended these complaints to add health care liability claims, at which point they did issue pre-suit notices and file certificates of good faith under the THCLA. Plaintiffs also assert that even if the THCLA were to apply to their original complaints, strict compliance is not necessary and prejudice must be shown before dismissal.

While defendants allege various specific deficiencies in the relevant complaints (including those that did bring THCLA claims from the start), the parties agreed in April 2014 to focus and limit their briefing to three key issues, leaving case-specific ones to be addressed at a later time. The issues are:

> (1) Whether plaintiffs were required to identify NECC and the Affiliated Parties[3] in pre-suit notices as health care providers that would be named as defendants and provide HIPAA-compliant[4] releases for those parties;
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> (2) Whether the pre-suit requirements set forth in Tenn. Code Ann. § 29-26-121 apply to plaintiffs filing complaints alleging only claims styled as products liability claims and, if so, whether failure to comply with such pre-suit requirements can be cured by a pleading amendment; and
>
> (3) Whether Tenn. Code Ann. § 29-26-122 requires that plaintiffs filing complaints alleging only claims styled as products liability claims file a certificate of good faith with the original complaint.

Resolving these questions requires analysis of whether plaintiffs' claims do in fact fall under the THCLA; if so, whether plaintiffs complied with the act's requirements; and if not, what the consequences of that noncompliance are.

### 1. The THCLA

The THCLA came to be in 2012, when the Tennessee legislature amended the Tennessee Medical Malpractice Act ("TMMA") to replace all references to "medical malpractice" and "medical malpractice action" with the terms "health care liability" and

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[3] The "Affiliated Parties" are certain individuals and entities closely associated with NECC. They include Barry Cadden, Lisa Cadden, Greg Conigliaro, Douglas Conigliaro, and Carla Conigliaro – who together founded and ran NECC – as well as pharmacist Glenn A. Chinn and related companies Ameridose, LLC, Medical Sales Management, Alaunus Pharmaceutical LLC, and GDC Holdings Inc. and/or GDC Properties Management LLC. See Master Compl. at ¶¶ 24-41.

[4] "HIPAA" is an acronym for the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, 110 Stat. 1936.

"health care liability action." See Act of April 23, 2012, ch. 798, § 7, 2012 Tenn. Pub. Acts. The act was also amended to provide definitions for "health care liability action," "health care provider," and "health care services":

> "Health care liability action" means any civil action, including claims against the state or a political subdivision thereof, alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, regardless of the theory of liability on which the action is based.

Tenn. Code Ann. § 29-26-101(a)(1).

> "Health care provider" means: (A) A health care practitioner licensed, authorized, certified, registered, or regulated under any chapter of titles 63 or 68 ... (D) The employee of a health care provider involved in the provision of health care services, including but not limited to physicians, nurses, licensed practical nurses, advance practice nurses, physician assistants, nursing technicians, pharmacy technicians, orderlies, certified nursing assistants, technicians and those physicians and nurses employed by a governmental health facility ...

Tenn. Code Ann. § 29-26-101(a)(2).

> Health care services to persons includes care by health care providers, which includes care by physicians, nurses, licensed practical nurses, pharmacists, pharmacy interns or pharmacy technicians under the supervision of a pharmacist, orderlies, certified nursing assistants, advance practice nurses, physician assistants, nursing technicians, and other agents, employees and representatives of the provider, and also includes staffing, custodial or basic care, positioning, hydration, and similar patient services.

Tenn. Code Ann. § 29-26-101(b).

It is unclear precisely what impact, if any, the changes in terms and insertion of definitions had on the scope of the THCLA. One Tennessee court has indicated that the replacement of "medical malpractice" with "health care liability" had no substantive effect on the operation of the statute, Moses v. Dirghangi, 430 S.W.3d 371, 380 n.4

(Tenn. Ct. App. 2013), and state courts have used the terms interchangeably in recent cases. However, as relevant here, there is also some suggestion that the amendments expanded the reach of the act to cover more than just claims of medical negligence.

For example, prior to the amendments, courts regularly differentiated between claims of medical malpractice and claims of "ordinary negligence." The Tennessee Supreme Court in Estate of French v. Stratford House, 333 S.W.3d 546, 556 (Tenn. 2011), a wrongful death suit regarding allegedly negligent care administered in a nursing home, noted that "[n]ot all cases involving health or medical care automatically qualify as medical malpractice claims." Rather,

> If the alleged breach of duty of care set forth in the complaint is one that was based upon medical art or science, training, or expertise, then it is a claim for medical malpractice. If, however, the act or omission complained of is one that requires no specialized skills, and could be assessed by the trier of fact based on ordinary everyday experiences, then the claim sounds in ordinary negligence. ... The [TMMA] applies only to those alleged acts that bear a substantial relationship to the rendition of medical treatment by a medical professional or concern medical art or science, training, or expertise.

Id. at 556-57. Thus, the court in Estate of French held that allegations pertaining to specialized medical or nursing skills and training, such as negligence in "assessing [the patient's] condition, developing her initial plan of care, and properly updating that plan to conform to changes in her condition do indeed sound in medical malpractice." Id. However, allegations that the nursing home staff, certified nursing assistants, failed to provide basic routine services and comply with the care plan's instructions constituted claims of ordinary negligence. Moreover, the court found that while the plaintiff could not assert a negligence per se claim in connection with her medical malpractice

allegation ("The effect of declaring conduct negligent per se is to hold that conduct is negligent as a matter of law, ... [which] conflicts with the TMMA's instruction that 'there shall be no presumption of negligence on the part of the defendant' in a medical malpractice action"), she could proceed on a negligence per se theory in support of her claims of ordinary negligence. Id. at 561.

Yet under the recent amendments, claims regarding the conduct of the certified nursing assistants in Estate of French, which the Tennessee Supreme Court held to be "ordinary negligence" claims, would arguably be considered part of a "health care liability action" and therefore subject to the THCLA. The Tennessee Court of Appeals confirmed as much in Parker v. Portland Nursing & Rehab., No. M2011-02633-COA-R9-CV, 2012 WL 3776800, at *4 n.4 (Tenn. Ct. App. Aug. 30, 2012), indicating that "[b]oth parties note that the passage of the Tennessee Civil Justice Act of 2011 [amending the TMMA] ended this distinction [between ordinary negligence and medical malpractice discussed in Estate of French] and created a new cause of action of a 'health care liability' claim." See also John W. Elder and Joshua R. Walker, The Tennessee Civil Justice Act of 2011: What a Difference a Day Made, 47-AUG TENN. B.J. 20, 22 (2011) (positing that while claims against a certified nursing assistant for failure to assure proper hydration and position as directed in a patient's plan of care would previously have been considered ordinary negligence claims, under the new amendments they would be subject to the statutory requirements of the THCLA).

As explored in greater detail infra, whether and to what extent the new THCLA similarly subsumes other types of civil claims is at the core of the parties' debate.

Defendants insist that the THCLA, by its plain language, was intended to be the exclusive remedy for plaintiffs bringing any civil claim against a health care provider related to the provision of health care. Plaintiffs dispute this contention, at least with respect to certain claims.

Where the THCLA does in fact apply, plaintiffs must comply with several statutory requirements in bringing their claims. At least 60 days before filing a complaint based upon health care liability, a plaintiff must give written notice of his or her potential health care liability claim to "each health care provider that will be named a defendant." Tenn. Code Ann. § 29-26-121(a)(1). This pre-suit notice must include:

> (A) The full name and date of birth of the patient whose treatment is at issue;
>
> (B) The name and address of the claimant authorizing the notice and the relationship to the patient, if the notice is not sent by the patient;
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> (C) The name and address of the attorney sending the notice, if applicable;
>
> (D) A list of the name and address of all providers being sent a notice; and
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> (E) A HIPAA compliant medical authorization permitting the provider receiving notice to obtain complete medical records from each other provider being sent a notice.

Id. at § 29-26-121(a)(2). The THCLA also has a requirement that:

> In any health care liability action in which expert testimony is required by § 29-26-115, the plaintiff or plaintiff's counsel shall file a certificate of good faith with the complaint. If the certificate is not filed with the complaint, the complaint shall be dismissed, as provided in subsection (c), absent a showing that the failure was due to the failure of the provider to timely provide copies of the claimant's records requested as provided in § 29-26-121 or demonstrated extraordinary cause.

Id. at § 29-26-122(a).[5] The statute instructs that failure to file a certificate of good faith in compliance with the THCLA makes an action subject to dismissal with prejudice. See id. § 29-26-122(c).

A plaintiff in a health care liability action has the burden of proving, by expert evidence:

> (1) The recognized standard of acceptable professional practice in the profession and the specialty thereof, if any, that the defendant practices in the community in which the defendant practices or in a similar community at the time the alleged injury or wrongful action occurred;
>
> (2) That the defendant acted with less than or failed to act with ordinary and reasonable care in accordance with such standard; and
>
> (3) As a proximate result of the defendant's negligent act or omission, the plaintiff suffered injuries which would not otherwise have occurred.

Id. at § 29-26-115(a). The act indicates that "there shall be no presumption of negligence on the part of the defendant," id. at § 29-26-115(c), and that "the jury shall be instructed that the claimant has the burden of proving, by a preponderance of the evidence, the negligence of the defendant," id. at § 29-26-115(d).

**2. Were plaintiffs required under the THCLA to identify NECC and**

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[5] Under Tenn. Code Ann. § 29-26-122(a):

> The certificate of good faith shall state that:
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> (1) The plaintiff or plaintiff's counsel has consulted with one (1) or more experts who have provided a signed written statement confirming that upon information and belief they:
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> (A) Are competent under § 29-26-115 to express an opinion or opinions in the case; and
>
> (B) Believe, based on the information available from the medical records concerning the care and treatment of the plaintiff for the incident or incidents at issue, that there is a good faith basis to maintain the action consistent with the requirements of § 29-26-115 ...

**the Affiliated Parties in pre-suit notices and provide HIPAA releases allowing defendants to obtain records from those parties?**

Plaintiffs' pre-suit notices to the Tennessee Clinic Defendants, Saint Thomas Entities, and Ascension Parties did not list NECC and the Affiliated Parties nor include HIPAA releases to obtain medical records from them. Defendants argue that these omissions run afoul of Tenn. Code Ann. § 29-26-121, which requires that the pre-suit notice include "a list of the name and address of all providers being sent a notice" and "a HIPAA compliant medical authorization permitting the provider receiving notice to obtain complete medical records from each other provider being sent a notice."

Plaintiffs argue that they were not required to identify NECC and the Affiliated Parties in the pre-suit notice nor provide HIPAA releases for them because their claims against NECC and company are not health care liability claims. Plaintiffs maintain that NECC and the Affiliated Parties acted as drug manufacturers, not as health care providers, and that their claims against them sound in products liability. As such, plaintiffs were not required to send them pre-suit notice under the THCLA, and consequently, were not required to identify those parties as "providers being sent notice" in their notices to defendants. Moreover, NECC and the Affiliated Parties expressly waived all state law pre-suit filing requirements, as confirmed by MDL Order No. 6. In any event, plaintiffs assert that defendants were not deprived of the opportunity to obtain medical records from NECC and the Affiliated Parties because those parties did not have any such records; and that since defendants failed to use even the few medical authorizations they did receive, they cannot show prejudice

resulting from the lack of authorizations from the remaining plaintiffs.

Defendants reply that NECC and the Affiliated Parties are "health care providers" as the term is defined in the statute. The claims against them are pled not expressly as "products liability" but as negligence, negligence per se, negligent supervision, and public nuisance, and defendants assert that the THCLA subsumed all such claims against health care providers for injury related to the provision of health care services under "health care liability." Even if plaintiffs are not suing NECC or the Affiliated Parties for health care liability, defendants argue that the trigger for pre-suit notice only requires that *a* health care provider be a named defendant in a complaint alleging health care liability against *some*one (and here, plaintiffs allege health care liability against the defendants). Defendants also dispute that NECC and the Affiliated Parties' unilateral waiver of pre-suit notice eliminated the need to identify them in the notices sent to other defendants since the requirement's primary purpose is to enable defendants to evaluate the suit and facilitate settlement. Because plaintiffs did not identify NECC and the Affiliated Parties in the pre-suit notices, defendants claim they were prejudiced in their evaluation of the case with respect to questions of comparative fault and venue.

In determining the nature and substance of a claim, Tennessee law directs courts to look at the "gravamen of the complaint," irrespective of the designations given the claims by the parties. Estate of French, 333 S.W.3d at 557. Under that approach, plaintiffs have the better of the argument. While NECC and the Affiliated Parties, by virtue of their status as pharmacies, pharmacists, or employees thereof, may fall under

the THCLA's technical definition of "health care providers," their role in these cases was not as providers but as the manufacturers and distributors of MPA. Plaintiffs did not have a patient-provider relationship with NECC or the Affiliated Parties and, indeed, were unlikely to have been aware of their existence at the time of the injections.[6] Plaintiffs' claims against NECC and the Affiliated Parties are not really about the provision of health care services, but about the defects of a product compounded and sold by NECC; the allegations against them claim negligence in "their design, compounding, sale, testing, marketing, and distribution of the recalled steroid medication," not in administering it to patients.[7] See, e.g., Pellicone, et al. v. Ameridose, et al., 1:13-cv-12916-RWZ, Docket # 1 ("Pellicone Compl.") at ¶ 202.

That plaintiffs may be bringing health care liability claims against other defendants does not mean that their claims against NECC and the Affiliated Parties are

[6] C.f. Kelley v. Middle Tennessee Emergency Physicians, P.C., 133 S.W.3d 587, 592 (Tenn. 2004) ("A physician-patient relationship is an 'essential' or 'necessary' element of a medical malpractice action."); Gunter v. Laboratory Corp. of America, 121 S.W. 636, 640 (Tenn. 2003). ("[N]ot all cases involving health or medical entities sound in medical malpractice.").

[7] An illustrative case, albeit one that precedes the 2012 amendment adding the definition of "health care provider" to the THCLA, is Debakker v. Hanger Prosthetics & Orthotics East, Inc., 688 F. Supp. 2d 789 (E.D. Tenn. 2010). The plaintiff, a purchaser of a defective leg brace, sued the manufacturer of the brace and an orthotist employed by the manufacturer. Plaintiff alleged that the orthotist, who fitted her for the brace, was negligent in failing to adequately and safely design, manufacture, inspect, and/or test the leg brace before selling and providing it to her; in failing to use reasonable care in fitting, modifying, and altering the brace; and in failing to adequate instruct and/or warn her as to the brace. She brought claims for negligence, strict products liability, and breach of warranty. The defendants filed for summary judgment, arguing that the case must be brought under the Tennessee Medical Malpractice Act because the orthotist was a "health care provider." The court disagreed, noting that the role of the orthotist differed from that of a health care provider: "In medical relationships like the one at issue is this case, the treating physician diagnoses the medical condition and provides medical advice to the patient. The orthotist, by contrast, merely carries out the orders of the treating physician." Id. at 792. Similarly, here, NECC and the Affiliated Parties did not provide treatment or medical services to patients (and in fact, had no direct interaction with them at all), but rather compounded and provided drug products to pain clinics and treating physicians in response to their order requests.

necessarily or automatically also health care liability claims. Because NECC and the Affiliated Parties are not being sued as health care providers and therefore were not sent pre-suit notice under the THCLA, plaintiffs did not need to include them on the pre-suit notices or HIPAA releases sent to defendants. The motions to dismiss by the Tennessee Clinic Defendants, Saint Thomas Entities, and Ascension Parties are therefore denied as to this point.

### 3. Do the pre-suit notice and good faith certificate requirements of the THCLA apply to plaintiffs' original complaints alleging only products liability claims?

The parties fiercely debate whether the THCLA has any application at all to plaintiffs' original complaints alleging only products liability claims against defendants. Plaintiffs explain that some complaints were initially filed only as products liability actions due to a timing complication. Under the Tennessee Products Liability Act of 1978 ("TPLA"), a one-year statute of limitations period begins to run on the date when a plaintiff discovers or reasonably should discover that he was injured by an unreasonably dangerous or defective product. There is no requirement of pre-suit notice under the TPLA. In contrast, the THCLA requires plaintiffs to give 60-day written notice prior to filing suit, after which the one-year statute of limitations is extended by an additional 120 days. In the case of some plaintiffs, their products liability claims would have expired before sufficient notice had been given on their health care liability claims; thus, out of an abundance of caution, these plaintiffs proceeded to file their TPLA claims while waiting for their THCLA claims to ripen, often expressly indicating that they intended to later amend their pleadings to add health care liability claims.

These plaintiffs then amended their complaints to add now-ripe THCLA claims and filed the appropriate documents required by that act.

Defendants assert that the products liability claims, from the start, were nonetheless governed by the THCLA, which they insist was intended to be the sole cause of action for claims against health care providers. They argue that because the act pertains to any suit against a health care provider claiming injury "related to" the provision of health care services "regardless of the theory of liability on which the action is based," Tenn. Code Ann. § 29-26-101(a)(1), plaintiffs' products liability claims must comply with the THCLA. Defendants also contend that they are not "sellers" under the TPLA, arguing instead that they are providers of professional services and that plaintiffs' claims (despite the "products liability" title) are, at bottom, about the provision of health care services.[8]

Plaintiffs, in contrast, insist that the THCLA pertains only to claims regarding the provision of health care services, not the sale of goods or products, which are governed by the TPLA. They note that their products liability claims arise from the defective and unreasonably dangerous condition of a pharmaceutical product, not from the services performed while administering that product to patients. Plaintiffs also maintain that the THCLA's certificate of good faith requirement only applies to health care liability actions in which "expert testimony is required," Tenn. Code Ann. § 29-26-122(a), related to the defendant's breach of standard of care. However, TPLA claims involve strict liability and do not require expert testimony as to a breach of the

[8] Whether plaintiffs can bring TPLA claims against defendants at all is addressed in the evaluation of defendants' motions to dismiss global claims. See infra Part II.B.1.a.

applicable standard of care.

Once again, we must look at the "gravamen of the complaint" with respect to these claims, Estate of French, 333 S.W.3d at 557, and consider the scope of the THCLA. The situation here mirrors the circumstances of Parker, 2012 WL 3776800, at *1-2, where the plaintiff filed an initial complaint in which she expressly and specifically stated that she was only asserting claims for ordinary negligence and was not asserting claims for medical malpractice. She later filed a separate complaint alleging medical malpractice and complying with the pre-suit requirements of the TMMA. The plaintiff sought to consolidate the two actions and then to amend her first complaint to add the medical malpractice claims. The trial court dismissed the second case on the ground that there was a prior lawsuit pending, and denied the plaintiff's motion to amend the first complaint because she failed to comply with the notice requirements of Tenn. Code Ann. § 29-26-121(a) prior to filing that suit. The appeals court reversed, finding that the plaintiff's first complaint indeed only asserted claims for ordinary negligence and therefore she was not required to comply with the TMMA for those claims: "Plaintiff was not required to give notice prior to filing her Ordinary Negligence Complaint and therefore to deny Plaintiff's motion to amend a complaint that did not require pre-suit notice to add claims for a separate cause of action in which pre-suit notice was complied with, creates an absurd result." Id. at *5.

As already noted above, the broad definitions of "health care liability action" and ""health care services" added to the THCLA in 2012 arguably eliminated the distinction between medical malpractice and ordinary negligence claims as they pertain to health

care services; now all such ordinary negligence claims presumably must proceed under the THCLA. See Parker, 2012 WL 3776800, at *4 n.4. Nonetheless, it is unclear whether the amended THCLA has had a similar effect on other types of civil claims against health care providers – claims which courts had, as with negligence, previously distinguished from medical malpractice claims under the TMMA.

For instance, in Abeyta v. HC Health Services of Tn., Inc., No. M2011-02254-COA-R3-CV, 2012 WL 5266321 (Tenn. Ct. App. Sept. 18, 2012), an involuntary commitment case, the trial court found that all of the plaintiff's claims were for medical malpractice and dismissed her complaint for failure to file a certificate of good faith. The appeals court reversed, finding that the plaintiff had made out claims for, among other things, medical battery, which "is not a medical malpractice claim governed by the TMMA," and negligence per se, "which is not governed by the TMMA." Id. at *9 and 11. The court noted in particular that a certificate of good faith was inapt for medical battery claims, given that expert testimony is not required to sustain such claims, and that the proof of standard of care for negligence per se was inconsistent with the TMMA's requirements. Id. The Sixth Circuit in Shuler v. Garrett, 743 F.3d 170 (6th Cir. 2014), similarly declined to apply health care liability requirements to a claim for medical battery despite the fact that the tort of medical battery, by definition, bears a substantial relationship to the rendition of medical treatment by a medical professional. The court found no indication that the Tennessee Supreme Court would extend the TMMA to cover all medical battery claims, and thus chose to "treat the medical battery claim ... as just that – a medical battery claim – rather than transmuting it into a medical

malpractice claim." Id. at 176. See also Barnett v. Elite Sports Medicine, No. M2010-00619-COA-R3-CV, 2010 WL 5289669, at *5 (Tenn. Ct. App. 2010) (determining that plaintiff stated a claim for battery, distinct from allegations of medical malpractice, and holding that certificate of good faith was therefore not required); Truth v. Eskioglu, 781 F. Supp. 2d 630, 635 n.10 (M.D. Tenn. 2011) ("Even if the [Medical Malpractice] Act required dismissal of the plaintiff's malpractice claims, at least a portion of her intentional misrepresentation claim would go forward. Regardless of whether a plaintiff has filed a certificate of good faith, the plaintiff's claims survive to the extent that they do not require expert testimony.").

The parties offer no case law, and I have uncovered none, addressing these issues with respect to the amended THCLA or to products liability claims specifically. The THCLA's new definitions are broad and can conceivably be interpreted to span a wide variety of claims and theories of liability. However, the historical treatment of other civil claims under the TMMA, the lack of explicit support for defendants' argument that the THCLA is now the sole cause of action against health care providers, and the different showing of proof required for products liability as opposed to claims under the THCLA all suggest that plaintiffs should be permitted to plead products liability claims as separate from health care liability. Like the court in Parker, I am loath to require compliance with THCLA requirements for non-THCLA claims, and therefore rule that plaintiffs did not have to give pre-suit notice or file certificates of good faith with original complaints alleging only products liability. See also Fleming v. Saini, No. W2013-01540-COA-R3-CV, 2014 WL 2592548, at *5 n.7 (Tenn. Ct. App. June 10, 2014) ("Trial

courts should be vigilant to guard against misuse of the TMMA as a vehicle for a defendants to obtain dismissal of a lawsuit that is not primarily a health care liability action."). Accordingly, the motions to dismiss by the Tennessee Clinic Defendants, Saint Thomas Entities, and Ascension Parties for failure to comply with the THCLA with respect to products liability claims are denied.

#### 4. What are the consequences of noncompliance with the THCLA?

In cases where the THCLA does apply, the parties dispute what should result from failure to comply with the act's pre-suit requirements. The Tennessee Clinic Defendants, Saint Thomas Entities, and Ascension Parties argue that the THCLA mandates strict compliance and defects cannot be cured by amendment. Plaintiffs, in contrast, assert that "substantial compliance" with the technical requirements of the statutes is sufficient and defendants must demonstrate prejudice to justify dismissal. Even if there are violations, plaintiffs posit that the court must conduct case-specific inquiries to determine whether noncompliance should be excused for extraordinary cause.

The Tennessee Supreme Court directs courts and parties to evaluate compliance with the THCLA according to the following process:

> The proper way for a defendant to challenge a complaint's compliance with Tennessee Code Annotated section 29-26-121 and Tennessee Code Annotated section 29-26-122 is to file a ... motion to dismiss. In the motion, the defendant should state how the plaintiff has failed to comply with the statutory requirements by referencing specific omissions in the complaint and/or by submitting affidavits or other proof. Once the defendant makes a properly supported motion under this rule, the burden shifts to the plaintiff to show either that it complied with the statutes or that it had extraordinary

> cause for failing to do so. Based on the complaint and any other relevant evidence submitted by the parties, the trial court must determine whether the plaintiff has complied with the statutes. If the trial court determines that the plaintiff has not complied with the statutes, then the trial court may consider whether the plaintiff has demonstrated extraordinary cause for its noncompliance.

Myers v. AMISUB (SFH), Inc., 382 S.W.3d 300, 307 (Tenn. 2012).

What exactly constitutes compliance, and the consequences of noncompliance, will depend on the nature of the violation. In general, the statutory requirements that a plaintiff give pre-suit notice and file a certificate of good faith are "mandatory, not directory," Myers, 382 S.W.3d at 308, so health care liability cases in which no notice was given or a certificate was not filed should be dismissed with prejudice, absent a showing of "extraordinary cause," Tenn. Code Ann. § 29-26-121(b) and § 29-26-122(a).

However, the THCLA's requirements as to the technical content of the pre-suit notice may, in some instances, be satisfied by substantial compliance. In Stevens ex. rel. Stevens v. Hickman Community Health Care Services, Inc., 418 S.W.3d 547 (Tenn. 2013), the defendant sought dismissal of the complaint because the plaintiff had failed to provide HIPAA-compliant medical authorizations as part of pre-suit notice as required by Tenn. Code Ann. § 29-26-121(a)(2)(E). The Tennessee Supreme Court determined that not all the subsections of the statute demanded strict compliance. Rather, the court found that "the touchstone of this analysis is whether a party's procedural error resulted in actual prejudice to an opposing party" – thus, strict compliance would be required only when "essential to avoid prejudicing an opposing litigant." Id. at 555. Because "[n]on-substantive errors and omissions [with the HIPAA

authorization] will not always prejudice defendants by preventing them from obtaining a plaintiff's relevant medical records," the court held that "a plaintiff must substantially comply, rather than strictly comply, with the requirements of Tenn. Code Ann. § 29-26-121(a)(2)(E)." Id. The Stevens court then evaluated the plaintiff's medical authorization and held that it did not substantially comply with the relevant subsection due to numerous errors and omissions. Id. at 556. Finding no extraordinary cause to excuse noncompliance, the court dismissed the complaint without prejudice.[9] Id. at 559-60.

Here, it is clear that in cases where plaintiffs were required to give pre-suit notice and/or file certificates of good faith and yet wholly failed to do so, such errors are fatal and should result in those complaints being dismissed. However, with respect to challenges regarding technical content of the pre-suit notice (including the provision of a HIPAA-compliant authorization), the court must determine the level of compliance required for that particular subsection, based on whether the "essence and fundamental purpose" of the notice requirement was met and whether strict compliance "is essential to avoid prejudicing the opposing litigant." Thurmond v. Mid-Cumberland Infectious Disease Consultants, PLC, et al., No. M2012-02270-SC-R11-CV, 2014 WL 1632183, at *7 (Tenn. Apr. 24, 2014). If I find that a plaintiff did in fact fail to comply (substantially or otherwise) with the THCLA's requirements, I must then evaluate

[9] In so doing, the Stevens court contrasted its remedy with the consequences of failing to file a certificate of good faith, which warrants dismissal with prejudice under the explicit language of the statute. Id. at 560. The court acknowledged, however, that the dismissal without prejudice effectively operated as a dismissal with prejudice because plaintiff's claim would then be time-barred. Id.

whether extraordinary cause[10] exists to excuse the violation. This may, as plaintiffs suggest, require case-specific inquiry. In any event, there are no allegations of noncompliance as to specific complaints currently before the court. As agreed to by the parties, such case-specific issues have been held in abeyance to be resolved at some later point in this litigation.

### B. Motions to Dismiss "Global Claims"

The Tennessee Clinic Defendants, Saint Thomas Entities, Ascension Parties, and Premier Defendants all filed motions to dismiss certain "global claims" that have been alleged in all or a substantial number of cases against them. Each motion shall be addressed separately below.

#### 1. The Tennessee Clinic Defendants' Motion to Dismiss Global Claims (Docket # 771)

Plaintiffs make nine global claims against the Tennessee Clinic Defendants: negligence, products liability, violation of the Tennessee Consumer Protection Act, medical battery, informed consent, civil conspiracy, vicarious liability (for the actions of NECC), "special duty," and health care liability. The Tennessee Clinic Defendants assert that all claims except those for health care liability should be dismissed for failure to state a claim upon which relief can be granted.

The Tennessee Clinic Defendants' primary argument for dismissal is that plaintiffs' claims, regardless of how they are labeled, fall under the purview of the

[10] While there is no precise definition of "extraordinary cause" and most courts have declined to find it, one court excused noncompliance where plaintiffs commenced suit during a time when the state of the law on the question of serving pre-suit notice was "unsettled, unclear, and potentially confusing." Brown v. Samples, No. E2013-00799-COA-R9-CV, 2014 WL 1713773, at *9 (Tenn. Ct. App. Apr. 29, 2014).

THCLA and therefore must comply with the act. The Tennessee Clinic Defendants assert that because the complaints all allege injury against them, "health care providers," as a result of the administration of medication, a "health care service," any claims that fail to comply with THCLA's requirements, or are somehow inconsistent with the statute, must be dismissed. In the alternative, even if dismissal is not warranted under the THCLA, the Tennessee Clinic Defendants urge dismissal of certain claims for failure to state a claim for various additional reasons.

**a. Products Liability**

Plaintiffs seek to hold the Tennessee Clinic Defendants strictly liable for the contaminated MPA under the Tennessee Products Liability Act of 1978 ("TPLA"). The Tennessee Clinic Defendants argue that they are not "sellers" of the medications they administer and that plaintiffs' claims are expressly contrary to the THCLA, which requires a plaintiff to prove the negligence of the defendant by expert testimony. In essence, the Tennessee Clinic Defendants maintain that plaintiffs cannot recover from them under a theory of strict products liability and instead must plead and prove their case in a manner consistent with the requirements of the THCLA.

The TPLA defines "product liability action" as "all actions brought for or on account of personal injury, death, or property damages caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing packaging or labeling of any product." Tenn. Code Ann. § 29-28-102. The term "includes, but is not limited to, all actions based upon the following theories: strict liability in tort; negligence; breach of warranty, express or

implied; breach of or failure to discharge a duty to warn or instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or under any other substantive legal theory in tort or contract whatsoever." Id. The seller of a product may be found strictly liable, with no proof of negligence, if the product causing injury to a person or property "is determined to be in a defective condition or unreasonably dangerous at the time it left the control" of the seller. Nye v. Bayer Cropscience, Inc., 347 S.W.3d 686, 693 (Tenn. 2011) (quoting Tenn. Code Ann. § 29-28-105(a)). A products liability action can only be brought against a non-manufacturer seller, however, in select situations, including (as is relevant here) when the manufacturer has been judicially declared insolvent. Tenn. Code Ann. § 29-28-106.

The Tennessee Clinic Defendants argue that they are not "sellers" of MPA and cannot be sued for products liability. A "seller" includes "a retailer, wholesaler, or distributor, and means any individual or entity engaged in the business of selling a product, whether such sales is for resale, or for use or consumption." Tenn. Code Ann. § 29-28-102(7). The Tennessee Clinic Defendants claim that, under Tennessee law, providers of professional services are not sellers of items used during the provision of those services. They cite two Tennessee cases in support: Parker v. Warren, 503 S.W.2d 938, 945 (Tenn. Ct. App. 1973), in which several carpenters were held not to be sellers of the defective lumber used to construct bleachers, and Delta Refining Co. v. Procon, Inc., 552 S.W.2d 387, 389 (Tenn. Ct. App. 1976), in which a general contractor was held not to be the "seller" of a defective pump, but rather "merely contracted with [the plaintiff] to purchase and install a pump which [the manufacturer]

would build according to specifications furnished by Plaintiff." The Tennessee Clinic Defendants acknowledge that Tennessee has not specifically addressed whether health care providers can be held strictly liable as sellers, but urge the court to nonetheless follow the example of numerous other jurisdictions that have explicitly held that health care providers are not sellers of the items consumed during the provision of health care services.

Plaintiffs, however, note that neither Parker nor Delta Refining held definitively that providers of professional services are not sellers, but rather that the specific defendants at issue in those cases were not "sellers" because they neither selected nor sold the subject products. In contrast, plaintiffs allege that the Tennessee Clinic Defendants were in fact engaged in "selling" MPA, selecting the steroid and charging patients for it separately and apart from monies charged for the services of the physicians administering the injections. They argue that patients visited the Tennessee clinics not to receive services, but to receive a product to relieve their back pain.

Plaintiffs also contend that unique provisions of the TPLA indicate that health care providers can be considered sellers of harmful or defective products. Section 103 of the TPLA, which sets forth time limitations on product liability actions, contains a special extension of the statute of repose for actions based on injury resulting from silicone gel breast implants:

> (c)(1) Any action against a manufacturer or seller for injury to person caused by a silicone breast implant must be brought within a period not to exceed twenty-five (25) years from the date such product was implanted; provided, that such action must be brought within four (4) years from the date the plaintiff knew or should have known of the injury.

> (2) **For purposes of this subsection (c) only**, "seller" does not include a hospital or medical facility where the procedure took place, nor does "seller" include a physician or other medical personnel involved in the procedure.

Tenn. Code Ann. § 29-28-103 (emphasis added). Plaintiffs assert that the specific carve-out of health care providers from the definition of "seller" in § 29-28-103 (c)(2) logically implies that health care providers *can* be held liable as sellers in cases involving products *other than* silicone breast implants.

This court's case law research did not unearth any Tennessee cases in which products liability claims were successfully brought against health care providers, nor any cases indicating that health care providers were categorically not sellers or could not be sued under the TPLA. The absence of a clear precedent prohibiting products liability actions against health care providers and the statutory language cited by plaintiffs above strongly militate against barring such claims.

Even assuming the Tennessee Clinic Defendants can be considered sellers, the question remains whether plaintiffs can bring TPLA claims in light of the THCLA. As already discussed to some degree in the prior section, the Tennessee Clinic Defendants contend that plaintiffs' products liability claims are clearly "related to the provision of ... health care services," Tenn. Code Ann. § 29-26-101(a)(1), and thus must comply with the THCLA. Moreover, they assert that plaintiffs' claims for strict products liability are contrary to the THCLA's requirement that a defendant's negligence be proven through expert testimony and therefore must be dismissed as inconsistent with the THCLA. Plaintiffs disagree with the Tennessee Clinic Defendants' broad reading of the THCLA's scope and insist that their products liability claims are

about the sale of a product, not the provision of health care services. They also argue that the inconsistency in burdens of proof between the two statutes does not warrant the dismissal of their TPLA claims but rather bolsters their position that products liability claims are separate from health care liability claims.

As of the date of this opinion, there are no cases dealing with the interaction of products liability claims with the THCLA. But the Tennessee Clinic Defendants cite to an older case, Burris v. Hospital Corp. of America, 773 S.W.2d 932 (Tenn. Ct. App. 1989), based on Tennessee's Medical Malpractice Review Board and Claims Act of 1975, the TMMA's predecessor. There, the plaintiff's wife underwent a surgical procedure to remove a portion of her lung; the surgeon used Teflon felt "pledgets" to support sutures in the closure of the lung. The presence of the pledgets enhanced the perpetuation of an infection in the lung, requiring its eventual removal and later contributing to the patient's death. The plaintiff brought a wrongful death action against the hospital, which argued that the case was barred by the statute of limitations of the Medical Malpractice Review Board and Claims Act. That act had previously contained a definition of "medical malpractice action" – repealed at the time of the lawsuit, but in effect at the time of the surgical procedure – as "any action for damages for personal injury or death as a result of any medical malpractice by a health care provider, whether based upon tort or contract law." Id. at 934. The plaintiff contended that the suit "involves the characteristics of a products liability case which is not comprehended within the Medical Malpractice Review Board and Claims Act," but the Tennessee Court of Appeals disagreed given the act's inclusive language of "whether based upon tort or

contract law." Id. The court reasoned that this phrase "must include all civil wrongs" and thus any ground stated by the plaintiff for the recovery of civil damages must be within the statutory definition of "medical malpractice." Id. at 935.

The Tennessee Clinic Defendants argue that the THCLA is even more expansive than the Medical Malpractice Review Board and Claims Act, and so the Burris court's reasoning applies here. This argument has some force. The THCLA's language is indeed broad, and a literal reading of "any civil action ... regardless of the theory of liability on which the action is based," Tenn. Code Ann. § 29-26-101(a)(1), seemingly could encompass plaintiffs' products liability claims. But plaintiffs contend that evaluating products liability claims as health care liability claims would unjustifiably expand the THCLA and conflict with decades of TPLA precedents without an express directive to that effect from the legislature.

"Federal courts hearing diversity matters should be extremely cautious about adopting substantive innovation in state law." Shuler, 743 F.3d at 176 (quoting Combs v. International Ins. Co., 354 F.3d 568, 578 (6th Cir. 2004). See also Dayton v. Peck, Stow, and Wilcox Co. (Pexto), 739 F.2d 690, 694 (1st Cir. 1984) ("[W]e are in particularly poor position, sitting as a federal court in a diversity case, to endorse [a] fundamental policy innovation .... Absent some authoritative signal from the legislature or the courts of [the state], we see no basis for even considering the pros and cons of innovative theories ...."). Here, plaintiffs have adequately stated claims for relief under the TPLA, apart from allegations of health care liability. Given the lack of controlling authority to the contrary, plaintiffs may proceed with their products liability claims as

separate from the THCLA.[11] See Shuler, 743 F.3d at 176.

**b. Tennessee Consumer Protection Act**

The Tennessee Clinic Defendants seek dismissal of plaintiffs' claims under the Tennessee Consumer Protection Act ("TCPA"), Tenn. Code Ann. § 47-181-101, et seq., as inconsistent with the THCLA. In the alternative, they assert that Tennessee law does not permit recovery for losses flowing from personal injury or wrongful death, nor allow claims concerning the provision of medical services, under the TCPA.

The TCPA makes unlawful "unfair or deceptive acts or practices affecting the conduct of any trade or commerce." Tenn. Code Ann. § 47-18-104. The act allows for individual private actions to recover actual damages for "an ascertainable loss of money or property, real, personal, or mixed, or any other article, commodity, or thing of value wherever situated, as a result of the use or employment by another person of an unfair or deceptive act or practice described in § 47-18-104(b)." Id. at § 47-18-109(a)(1).

The master complaint alleges that "[h]ad Clinic Related Defendants not engaged in the deceptive conduct described herein, Plaintiffs would not have allowed for the administration of NECC Contaminated Drugs, and would not have incurred related medical costs and injury, and at times, death." Master Compl. at ¶ 260. The Tennessee Clinic Defendants are correct that plaintiffs cannot recover under the TCPA

[11] Notwithstanding this ruling, plaintiffs cannot prosecute their products liability claims against defendants who are not alleged to have sold the MPA, i.e., the charge for the drug did not come from them. It is unclear at this juncture who those individuals or entities may be.

for damages flowing from personal injury or wrongful death.[12] In Kirksey v. Overton Pub, Inc., 804 S.W.2d 68, 73 (Tenn. Ct. App. 1990), the Tennessee Court of Appeals rejected the plaintiffs' assertion that their son's life was "a thing of value" under § 47-18-109 and found that the TCPA was intended to be used only by a person claiming damages for loss of money or property, not in a wrongful death action. Similarly, in Akers v. Prime Succession of Tennessee, 387 S.W.3d 495, 509 (Tenn. 2012), the Tennessee Supreme Court held that "an action does not lie under the TCPA for emotional distress in the absence of pecuniary damages." See also Howard v. R.J. Reynolds Tobacco Co., No. 1:05CV-27, 2005 WL 2088909, at * 3 (E.D. Tenn. Aug. 25, 2005) ("[T]he Court must dismiss Plaintiff's claims to the extent he seeks to recover for injuries to his person resulting from [defendant's] alleged violations of the TCPA."); Birdsong v. Eli Lilly and Co., No. 3:10-01182, 2011 WL 1259650 at *3 (M.D. Tenn. Mar. 31, 2011) (dismissing TCPA claims where plaintiffs sought to recover for personal injuries allegedly suffered as a result of taking defendants' medication); Riddle v. Lowe's Home Centers, Inc., 802 F. Supp. 2d 900, 909 (M.D. Tenn. 2011) (dismissing TCPA claims for bodily injuries, including sums consequently incurred for medical care, attendance, and lost income).

The Tennessee Clinic Defendants also assert that plaintiffs' TCPA claims must be dismissed because the act does not provide a remedy for claims related to the provision of medical care. In support, they cite Constant v. Wyeth, 352 F. Supp. 2d 847, 853 (M.D. Tenn. 2003), where the court held that "medical malpractice claims may

[12] Plaintiffs also allege losses for the monies used to purchase the MPA from the Tennessee Clinic Defendants. Master Compl. at ¶ 263. These losses may be recoverable under the TCPA.

not be recast as consumer protection act claims" because "the actual practice of medicine does not affect trade or commerce." However, the Constant court acknowledged that it was not making a blanket holding that physicians are entirely immune from TCPA claims; "[r]ather, they are only immune when the plaintiff's allegations concern the actual provision of medical services." Id. at n.10. Here, again, plaintiffs allege not only that the Tennessee Clinic Defendants provided medical care, but that they were sellers of a product (MPA), the nature, quality, and characteristics of which they allegedly misrepresented. They claim that the Tennessee Clinic Defendants failed to provide accurate disclosures of all material information before patients agreed to be injected with the MPA – including important product safety information – and in many cases represented that patients were receiving FDA-approved Depomedrol and not NECC's compounded MPA. See Master Compl. at ¶¶ 246-253. Such alleged misrepresentations focus on the drug itself, as opposed to the provision of medical care or the Tennessee Clinic Defendants' conduct in administering the drug.

As with plaintiffs' products liability claims, there is potential for overlap with health care liability here. But while "the proper administration of prescribed medicine is, in fact, medical treatment," Dunlap v. Laurel Manor Health Care, Inc., 422 S.W.3d 577, 581 (Tenn. Ct. App. 2013), the heart of plaintiffs' TCPA claims is not that the Tennessee Clinic Defendants failed to properly administer the MPA, but that they sold the MPA to plaintiffs on the basis of false and incomplete information. Because these allegations do not really pertain to the provision of health care services, the THCLA

does not apply.

Plaintiffs' TCPA claims are dismissed to the extent they seek recovery for personal injuries or wrongful death. However, claims for the recovery of monies used to purchase MPA survive.

**c. Battery and Failure to Warn (Lack of Informed Consent)**

The Tennessee Clinic Defendants contend that plaintiffs' medical battery and failure to warn (lack of informed consent) claims should be dismissed as inconsistent with the THCLA and for failure to state a claim.

As previously discussed, supra at Part III.A.3, courts have historically differentiated between medical battery and medical malpractice, holding that the former did not fall within the TMMA. See Barnett, 2010 WL 5289669, at *5; Shuler, 743 F.3d at 176. It is unclear whether the recent amendment of the THCLA had any effect on that stance as there are no cases addressing medical battery in relation to the revised statute.

In any event, the Tennessee Clinic Defendants argue persuasively that plaintiffs have not stated a claim for medical battery. Tennessee distinguishes between claims for medical battery, "cases in which a doctor performs an unauthorized procedure," and claims for lack of informed consent, "cases in which the procedure is authorized but the patient claims that the doctor failed to inform the patient of any or all the risks inherent in the procedure." Blanchard v. Kellum, 975 S.W.2d 522, 524 (Tenn. 1998). If the patient was aware that the doctor was going to perform the procedure and authorized performance of that procedure, the case is not one of medical battery. Id. ("The

primary consideration in a medical battery case is simply whether the patient knew of and authorized a procedure.").

Plaintiffs do not allege that they did not know that the Tennessee Clinic Defendants would administer an epidural steroid injection, nor do plaintiffs allege that they did not authorize the Tennessee Clinic Defendants to perform the epidural steroid injection procedure. Instead, plaintiffs claim that they were "unaware of the substantial health and safety risk inherent in the use of NECC Contaminated Drugs" and "did not consent to the injection of contaminated drugs into their bodies." Master Compl. at ¶ 297. In short, plaintiffs do not contend that they did not consent to the procedure, but that they were not informed of the use of compounded or contaminated medication in that approved procedure. Such allegations do not state a claim for medical battery under Tennessee law, and plaintiffs' battery claims must be dismissed.

As for the lack of informed consent claims, plaintiffs allege that the Tennessee Clinic Defendants failed to warn them that they were being administered "an unsafe, unreasonably dangerous drug compounded by NECC rather than a high quality drug produced by an FDA regulated manufacturer" and failed to inform them of "the risks and benefits of the procedure[] before it was performed." Master Compl. at ¶¶ 301-302. Such allegations must be established with expert testimony regarding "the usual and customary information given to patients to procure consent in similar situations." Blanchard, 975 S.W.2d at 524. The Tennessee Clinic Defendants correctly point out that lack of informed consent claims are governed by the THCLA. See Tenn. Code

Ann. § 29-26-118.[13] See also Bryant v. HCA Health Services of N. Tennessee, Inc., 15 S.W.3d 804, 808 (Tenn. 2000) ("The claim [of lack of informed consent] ... involves matters of medical science and requires specialized skills not ordinarily possessed by lay persons. Accordingly, the defendant is within the purview of the Medical Malpractice Act ('Act'), and the plaintiffs' claims are governed by that Act."). This does not mean plaintiffs cannot proceed on their theory of lack of informed consent, but rather that those allegations will be subsumed under their claims for health care liability and evaluated under the requirements and framework of the THCLA. See, e.g., White v. Beeks, No. E2012-02443-COA-R3-CV, 2013 WL 6451764 (Tenn. Ct. App. Dec. 9, 2013) (applying health care liability action requirements to claim for lack of informed consent).

The Tennessee Clinic Defendants additionally assert, however, that the lack of informed consent claims against certain defendants should be wholly dismissed. In Bryant, 15 S.W.3d at 808, the Tennessee Supreme Court, in evaluating Tenn. Code Ann. § 29-26-118, concluded that "the language of the statute suggests that the legal duty to obtain consent is imposed only on the physician who orders or directs the surgical procedure"; the court held that "mere status as one involved in a patient's care is insufficient to trigger a statutory duty under the informed consent statute" and a

[13] That section provides that:

> In a health care liability action, the plaintiff shall prove by evidence as required by § 29-26-115 that the defendant did not supply appropriate information to the patient in obtaining informed consent (to the procedure out of which plaintiff's claim allegedly arose) in accordance with the recognized standard of acceptable professional practice in the profession and in the speciality, if any, that the defendant practices in the community in which the defendant practices and in similar communities.

Tenn. Code Ann. § 29-26-118.

hospital generally is not required to procure a patient's informed consent to procedures "ordered and performed by non-employee doctors." Id. at 809-10. The Tennessee Clinic Defendants therefore contend that informed consent claims against STOPNC, Ms. Schamberg, SSC, and Dr. Lister's Practice should be dismissed, since those entities and individuals were neither the physicians nor the employers of the physicians who ordered and administered the MPA injections.[14] Plaintiffs offer no response to this argument and do not deny that the identified defendants lacked a duty to obtain consent under Tennessee law. As such, claims based on lack of informed consent against those defendants are dismissed. See Hinkle v. Kindred Hosp., No. M2010-02499-COA-R3-CV, 2012 WL 3799215, at *17 (Tenn. Ct. App. Aug. 31, 2012) (dismissing lack of informed consent claims against hospital that was not involved in making the decision to conduct procedure; "while hospital employees may have been the ones to actually carry out those the [non-employee] doctor's orders, they neither had the capacity nor the duty to obtain informed consent from the patient.").

**d. Ordinary Negligence and Gross Negligence**

Plaintiffs bring claims of ordinary negligence and gross negligence against the Tennessee Clinic Defendants, alleging that they, among other things, failed to appropriately investigate NECC prior to procuring drugs from the pharmacy; failed to follow certain policies and procedures to ensure such drugs were safe; failed to adequately supervise and train employees and agents who ordered the drugs; failed to promptly notify plaintiffs that they were injected with potentially contaminated steroids;

[14] The Tennessee Defendants also seek dismissal of informed consent claims against Howell Allen in certain cases where Dr. Culclasure did not perform injections.

and generally failed to exercise reasonable care or conduct due diligence to ensure they were not injecting contaminated and dangerous drugs into their patients. See Master Compl. at ¶¶ 226-238. These allegations pertain to the Tennessee Clinic Defendants' provision of health care services and thus fall within the purview of the THCLA. Plaintiffs' negligence claims, though they need not be entirely dismissed, will be evaluated under the THCLA and against the recognized standard of acceptable professional practice as required by the act.

**e. Duty to Prevent Foreseeable Harm**

Sixty-six of the complaints allege that the Tennessee Clinic Defendants, by virtue of a special relationship with their patients, owed a duty to protect them from foreseeable harm caused by NECC. Plaintiffs claim the Tennessee Clinic Defendants breached that duty by ignoring the risks of bulk pharmacy compounding, purchasing injectable steroids from NECC in bulk without individual prescriptions, and conspiring with NECC to hide its wrongful conduct from regulators. See, e.g., Pellicone Compl. at ¶¶ 191-199. Plaintiffs assert that the Tennessee Clinic Defendants are therefore jointly and severally liable for all harm caused by NECC's intentional misconduct. In response, the Tennessee Clinic Defendants argue that these claims fall under the THCLA and that Tennessee law does not impose a special duty on health care providers to protect a patient from the intentional actions of a third party.

Under Tennessee law, persons generally have no duty to act to protect others from dangers or risks except for those they themselves have created. Satterfield v. Breeding Insulation Co., 266 S.W.3d 347, 357 (Tenn. 2008). Nonetheless, "exceptions

arise when certain special relationships exist between the defendant and either the person who is the source of the danger or the person who is foreseeably at risk from the danger." Id. at 359. The Tennessee Clinic Defendants maintain that the special duty arising from the physician-patient relationship is limited to the *protection of third parties* from the reasonably foreseeable actions of the patient and does not flow the other way. See Bradshaw v. Daniel, 854 S.W.2d 865, 872 (Tenn. 1993) (physician-patient relationship sufficient to impose an affirmative duty on physician to warn identifiable third persons in the patient's immediate family against foreseeable risks emanating from a patient's illness). Plaintiffs, however, point to Limbaugh v. Coffee Medical Center, 59 S.W.3d 73, 81 (Tenn. 2001), where a nursing home was held to have acted negligently in failing to take reasonable precautions to protect a resident from the foreseeable risk that she would be assaulted by a staff member known to be physically aggressive. There is no indication that health care providers like the Tennessee Clinic Defendants would only be obligated to protect others from their patients. Rather, "[t]hese relationships create an affirmative duty *either* to control the person who is the source of the danger *or* to protect the person who is endangered." Satterfield, 266 S.W.3d at 359-60 (emphasis added).

There will be no liability "where the defendant neither knows nor has the reason to foresee the danger or otherwise know that precautions are called for." Limbaugh, 59 S.W.3d at 80 (quoting W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 56, at 385). The Tennessee Clinic Defendants argue that even if a special relationship existed between them and their patients, plaintiffs point to no facts

indicating that the Tennessee Clinic Defendants had actual knowledge that made the contamination of the MPA foreseeable. However, plaintiffs have alleged in their complaints that the dangers of bulk pharmacy compounding were well known in the medical community; that the Tennessee Clinic Defendants did not conduct appropriate due diligence or investigation into NECC, which had a history of adverse events, prior to purchasing the steroids; and that the Tennessee Clinic Defendants conspired with NECC to violate patient safety requirements by sending false lists of patients to NECC to obtain orders of MPA. See, e.g., Pellicone Compl. at ¶¶ 79, 111-118, 130-136, 161-163, 187-188, 193-194. These allegations, taken as true, are sufficient to make foreseeable to the Tennessee Clinic Defendants the risk that the MPA being given to their patients was somehow deficient or unsafe.

Plaintiffs' claims for duty to prevent foreseeable harm are essentially grounded in negligence and pertain to the provision of health care services, which would place them squarely within the THCLA. Thus, the claims will be evaluated as health care liability claims, albeit under the theory of the duty to prevent foreseeable harm.

**f. Civil Conspiracy**

Plaintiffs' allegations of civil conspiracy, supplemented by an amendment filed on January 31, 2014 (Docket # 833), assert that the Tennessee Clinic Defendants[15] knew that NECC was a compounding pharmacy and that MPA is a controlled substance that cannot be dispensed without a prescription under Massachusetts law and the

[15] While the master complaint and plaintiffs' briefs indicate that the civil conspiracy claim is brought against the "Tennessee Defendants" or "Clinic Related Defendants," the actual allegations only recite specific actions by STOPNC, Dr. Culclasure, and Ms. Schamberg while stating that "[u]pon information and belief, the other Clinic Related Defendants had similar communications with NECC." Master Compl. at ¶ 349.

requirements of the Massachusetts Board of Registration in Pharmacy, as well as Tennessee law. See Master Compl. at ¶¶ 337-351. Nonetheless, the Tennessee Clinic Defendants allegedly acted in concert with the NECC to violate state and federal law by using "bogus" patient lists to obtain bulk orders of MPA instead of providing patient-specific names, information, and prescriptions as required by law. For example, plaintiffs allege that in early- to mid-2012, an NECC representative informed Ms. Schamberg that NECC needed to receive lists of patients with each order of MPA in order to comply with the Massachusetts Board of Pharmacy requirements. When Ms. Schamberg told the NECC representative that she could not predict which patients would receive MPA and therefore could not provide corresponding lists, the NECC representative allegedly indicated that any list of patient names would suffice. As a result, STOPNC allegedly sent NECC lists of patients' names and addresses even though the listed patients did not necessarily receive MPA and were, in some cases, fictitious (e.g., "Mickey Mouse").

Plaintiffs allege that the Tennessee Clinic Defendants knew or should have known that their conduct violated state and federal law, and that both defendants and NECC knew of each other's common intent to use the falsified patient lists to circumvent prescription requirements. Plaintiffs further allege that the conspiracy was a proximate and legal cause to their harm; had the Tennessee Clinic Defendants and NECC abided by the law requiring individual prescriptions, NECC would not have logistically been able to produce and sell MPA in bulk, and the Tennessee Clinic Defendants would have purchased safer, albeit more expensive, MPA from a more

reputable, FDA-regulated source, thereby avoiding the fungal meningitis outbreak.

Plaintiffs have alleged with adequate specificity that the Tennessee Clinic Defendants conspired with NECC to accomplish an unlawful purpose – to obtain MPA in violation of state and federal laws requiring specific patient prescriptions – including facts indicating the co-conspirators' knowledge of the law and their common intent to avoid it. However, the Tennessee Clinic Defendants are correct that plaintiffs fail to allege an actionable underlying tort. "It is a general rule that conspiracy cannot be made the subject of a civil action, unless something is done which, without the conspiracy, would give a right of action. The damage done is the gist of the action, not the conspiracy ... [T]he simple act of conspiracy does not furnish a substantive ground of action." Levy v. Franks, 159 S.W.3d 66, 82 (Ct. App. Tenn. 2004) (quoting Tenn. Pub. Co. v. Fitzhugh, 52 S.W.2d 157, 158 (Tenn. 1932)). Here, plaintiffs do not identify an underlying wrongful tort for the conspiracy and do not allege that any of the violated statutes or regulations provides a private right of action.[16] "It cannot be that a conspiracy to do a thing is actionable where the thing itself would not be." Felts v. Paradise, 158 S.W.2d 727, 729 (Tenn. 1942). See also In re Orthopedic Bone Screw Products Liability Litigation, 193 F.3d 781, 789-90 (3d Cir. 1999) ("[W]e are unaware of any jurisdiction that recognizes civil conspiracy as a cause of action requiring no

[16] The Tennessee Clinic Defendants opine that the only conceivable actionable tort alleged by plaintiffs' conspiracy allegations is fraud, and that plaintiffs have failed to adequately plead an intent to defraud.

separate tortious conduct. To the contrary, the law uniformly requires that conspiracy claims be predicated upon an underlying tort that would be independently actionable against a single defendant. Because plaintiffs here could not sue an individual defendant for an alleged violation of the FDCA, it follows that they cannot invoke the mantle of conspiracy to pursue the same cause of action against a group of defendants. A claim of civil conspiracy cannot rest solely upon the violation of a federal statute for which there is no corresponding private right of action.").

As such, plaintiffs' civil conspiracy claims are dismissed.[17]

**g. Vicarious Liability**

Finally, plaintiffs allege that NECC was an agent of the Tennessee Clinic Defendants and, therefore, the Tennessee Clinic Defendants are vicariously liable for the actions of NECC. See Master Compl. at ¶¶ 329-336. They claim that a consensual fiduciary relationship arose when the Tennessee Clinic Defendants contracted with NECC to procure compounded drugs from NECC for their patients, and that NECC consented to act as the Tennessee Clinic Defendants' agent, and in their

[17] The Tennessee Clinic Defendants also claim that many of plaintiffs' civil conspiracy claims are barred by the statute of limitations because they were brought more than one year after "the last overt act committed by the co-conspirators in furtherance of the conspiracy." Swafford v. Memphis Individual Practice Ass'n, No. 02A01-9612-CV-00311, 1998 WL 281935, at * 12 (Tenn. Ct. App. Jun. 2, 1998). Plaintiffs counter that the Tennessee Defendants are mistaken and that under controlling case law, the statute of limitations for tort action, including civil conspiracy, is triggered "when the injury occurs or is discovered." McCroskey v. Bryant Air Conditioning Co., 524 S.W.2d 487, 490 (Tenn. 1975). See also Hill v. A.O. Smith Corp., 801 F.2d 217, 224 (6th Cir. 1986) (following McCroskey in civil conspiracy case); Blakeney v. Kassel, 1991 WL 87978 (Tenn. Ct. App. 1991) (same). Plaintiffs' position appears to have better support. The civil conspiracy claims of Tennessee victims who brought suit less than one year after they first began suffering symptoms, and less than one year before information about the alleged conspiracy was first discovered, were timely filed.

interest, when compounding and delivering its drugs. The master complaint also alleges that the Tennessee Clinic Defendants controlled the procurement of the drugs from NECC and that NECC acted within the scope of its agency when it negligently compounded drugs on behalf of the Tennessee Clinic Defendants. Id. at ¶¶ 330-336.

The Tennessee Clinic Defendants argue that plaintiffs have failed to plead sufficient facts to establish an agency relationship. They cite to seven factors identified in McInturff v. Battle Ground Academy of Franklin, No. M2009-00504-COA-R3-CV, 2009 WL 4878614 (Tenn. Ct. App. Dec. 16, 2009), as reflective of an agency relationship and contend that plaintiffs' allegations do not support any of them.[18] Plaintiffs, however, assert that the seven-factor test relied upon by the Tennessee Clinic Defendants pertains specifically to determining whether a relationship is that of employer-employee or general contractor-independent contractor, and it is not universally used to weigh agency in all instances. Rather, the concept of agency "in its broadest sense includes every relation in which one person acts for or represents another." Kerney v. Aetna Cas. & Sur. Co., 648 S.W.2d. 247, 253 (Tenn. Ct. App. 1982) (quoting Howard v. Haven, 281 S.W.2d 480, 485 (Tenn. 1955)). "Whether an agency exists 'is a question of fact under the circumstances of the particular case; and whether an agency has been created is to be determined by the relation of the parties as they in fact exist under their agreement or acts.'" White v. Revco Discount Drug

[18] The factors are: (1) the right to control the conduct of the work; (2) the right of termination; (3) the method of payment; (4) the freedom to select and hire helpers; (5) the furnishing of tools and equipment; (6) the self-scheduling of work hours; and (7) the freedom to render services to other entities. McInturff, 2009 WL 4878614, at *3.

Ctrs, Inc., 33 S.W.3d 713, 723 (Tenn. 2001) (quoting McCay v. Mitchell, 463 S.W.2d 710, 715 (Tenn. 1970)).

In any event, the principal's right to control the actions of the agent is "the essential test" in determining whether an agency relationship exists, Jack Daniel Distillery, Lem Motlow, Prop. v. Jackson, 740 S.W.2d 413, 416 (Tenn. 1987), though also important is the principal's "exercise of actual control over the agent," White, 33 S.W.3d at 723. Plaintiffs here allege neither adequately. They claim that the Tennessee Clinic Defendants "controlled the procurement of drugs from NECC to be sold and administered to their patients," Master Compl. at ¶ 335, but absent from the complaint are any facts indicating that the Tennessee Clinic Defendants had any right of control, or actually exercised any control, over NECC and its conduct. The relationship between NECC and the Tennessee Clinic Defendants as described in the complaint is essentially that of a manufacturer or vendor selling its products to a purchaser, not of an agent acting on behalf of or under the direction of a principal. Plaintiffs' conclusory allegations are insufficient to make out a claim for vicarious liability.

### 2. The Saint Thomas Entities' and Ascension Parties' Motions to Dismiss Global Claims (Docket ## 893 and 895)

The Saint Thomas Entities are named in several plaintiffs' complaints based on their relationship with STOPNC, a Tennessee clinic that administered the MPA injections. Plaintiffs allege that the Saint Thomas Entities are vicariously liable under the doctrine of respondeat superior for the actions of STOPNC. Specifically, they claim

that STOPNC and its physicians, nurses, and employees were the alter egos and/or the actual or apparent agents of the Saint Thomas Entities for the following reasons:

- The Saint Thomas Network is a co-owner of STOPNC.
- The Saint Thomas Entities and STOPNC share the common "St. Thomas" name.
- STOPNC is located inside the Saint Thomas Medical Plaza on St. Thomas Hospital campus.
- The CEO of St. Thomas Hospital is on the Board of Governors of STOPNC.
- The Medical Director of St. Thomas Hospital regularly attended STOPNC's Board of Governors meetings.
- STOPNC conducted its Board of Governors meetings in the St. Thomas Hospital board room.
- There was no notice to patients of STOPNC that St. Thomas Hospital was not the provider of care or that care provided by STOPNC was not subject to the control or supervision of St. Thomas Hospital.
- Saint Thomas Health/Network handles STOPNC's contracting and finances.
- Once the fungal meningitis outbreak occurred, STOPNC instructed patients to report to St. Thomas Hospital emergency room for evaluation and treatment.
- STOPNC is grossly undercapitalized and unable to meet its obligations to the fungal meningitis victims, and STOPNC was used as a business conduit designed to enrich Saint Thomas and Howell Allen while shifting the risk of loss to patients.

See, e.g., Reed v. Ameridose, et al., 1:13-cv-12565-RWZ, Docket # 1 ("Reed Compl.") at ¶¶ 275-277, 284-286.

Plaintiffs' claims against the Ascension Parties – Ascension Health Alliance and

Ascension Health – are in turn based on their relationship with the Saint Thomas Entities. Plaintiffs assert that the Ascension Parties "owned, operated, managed and/or simply did business, in part, as Saint Thomas Health, and/or Saint Thomas Network, and/or Saint Thomas West Hospital." See, e.g., Russell, et al. v. Unifirst Corp, et al., No. 1:13-cv-12794-RWZ, Docket # 1 ("Russell Compl.") at ¶ 241. Their allegations additionally state that:

- Ascension Health lists Saint Thomas Health as one of its "Hospitals and Facilities" on its website.
- On Ascension Health's IRS Form 990, Schedule R, Part I, Ascension Health is listed as the "direct controlling entity" of Saint Thomas Health.
- On Ascension Health's IRS Form 990, Schedule R, Part III "Identification of Related Organizations Taxable as a Partnership," STOPNC is one of the entities listed.

Russell Compl. at ¶¶ 241-243.

The Saint Thomas Entities argue plaintiffs have not alleged a sufficient factual basis for imposing vicarious liability and thus all claims against them should be dismissed. The Ascension Parties essentially adopt the arguments of the Saint Thomas Entities in asserting that claims against them should likewise be dismissed.

**a. Alter Ego Theory**

Plaintiffs allege that STOPNC is the alter ego of the Saint Thomas Entities. Tennessee law sets forth three required elements for alter ego liability:

> (1) The parent corporation, at the time of the transaction complained of, exercises complete dominion over its subsidiary, not only of finances, but of policy and business practice in respect to the transaction under attack, so that the corporate entity, as to that transaction, had no separate mind, will

or existence of its own.

> (2) Such control must have been used to commit fraud or wrong, to perpetuate the violation of a statutory or other positive legal duty, or a dishonest and unjust act in contravention of third parties' rights.
>
> (3) The aforesaid control and breach of duty must proximately cause the injury or unjust loss complained of.

Continental Bankers Life Ins. Co. of the South v. Bank of Alamo, 578 S.W.2d 625, 632 (Tenn. 1979). Other relevant and non-exclusive factors include:

> (1) whether there was a failure to collect paid in capital; (2) whether the corporation was grossly undercapitalized; (3) the nonissuance of stock certificates; (4) the sole ownership of stock by one individual; (5) the use of the same office or business location; (6) the employment of the same employees or attorneys; (7) the use of the corporation as an instrumentality or business conduit for an individual or another corporation; (8) the diversion of corporate assets by or to a stockholder or other entity to the detriment of creditors, or the manipulation of assets and liabilities in another; (9) the use of the corporation as a subterfuge in illegal transactions; (10) the formation and use of the corporation to transfer to it the existing liability of another person or entity; and (11) the failure to maintain arms length relationships among related entities.

Federal Deposit Ins. Corp. v. Allen, 584 F. Supp. 386, 397 (E.D. Tenn. 1984). "'Generally, no one factor is conclusive in determining whether or not to disregard a corporate entity'; rather, the courts typically rely upon a combination of factors in deciding such an issue." Oceanics Schools, Inc. v. Barbour, 112 S.W.3d 135, 140 (Tenn. Ct. App. 2003) (quoting Schlater v. Haynie, 833 S.W.2d 919, 925 (Tenn. Ct. App. 1991)).

The Saint Thomas Entities argue that plaintiffs' allegations, even if proven, fall short of Tennessee's high standard for piercing the corporate veil. They contend that,

at bottom, all plaintiffs can point to are a common name, proximity of facilities, and partial ownership. The Saint Thomas Entities also maintain that Tennessee law requires showing that the corporate form was misused to "sanction a fraud, injustice, or equivalent misfeasance," Southeast Texas Inns, Inc. v. Prime Hospitality Corp., 462 F.3d 666, 673 (6th Cir. 2006), and that the "real indicia of alter ego – like commingling of property, undercapitalization, and diversion of assets" are lacking here, Docket # 894 at 13.

Plaintiffs' allegations do not sufficiently set forth the elements necessary to apply the alter ego theory. While they note some connections between the Saint Thomas Entities and STOPNC, no facts alleged show that the former exercised such control over the latter such that "the two entities are in fact identical or indistinguishable," Edmunds v. Delta, L.L.C., 403 S.W.3d 812, 829 (Tenn. Ct. App. 2012), or that STOPNC had "no separate mind, will, or existence of its own," Continental Bankers, 578 S.W.2d at 632. This lack of complete dominion is further highlighted by the fact that STOPNC was co-owned, staffed, and managed by Howell Allen.

The alter ego allegations against the Ascension Parties are similarly weak. Aside from the conclusory statement that the Ascension Parties "owned, operated, managed and/or simply did business, in part, as Saint Thomas Health, and/or Saint Thomas Network, and/or Saint Thomas West Hospital," plaintiffs offer little to show that the Saint Thomas Entities were essentially alter egos of their parent company. The references to Saint Thomas Health on the Ascension Parties' IRS forms, even if true,

neither suggest that the Ascension Parties exercised the kind of complete dominion over the Saint Thomas Entities necessary to find alter ego liability nor speak to the other relevant factors. At most, they simply indicate that Saint Thomas Health is owned by Ascension Health and that STOPNC is a related entity for the purposes of federal taxation.

Plaintiffs' allegations, to the extent they rely on the alter ego theory, fail to state a claim for vicarious liability.

**b. Agency Theory**

Plaintiffs fare better under an agency theory of vicarious liability. As previously discussed, the concept of agency "includes every relation in which one person acts for or represents another." Kerney, 648 S.W.2d at 253 (Tenn. Ct. App. 1982). Plaintiffs assert that STOPNC, Dr. Culclasure, and Ms. Schamberg were actual and or apparent agents[19] of the Saint Thomas Entities.

The complaints allege that the Saint Thomas Entities owned and operated STOPNC, managed the contracting and finances of the clinic, and had several connections to the clinic's Board of Governors. STOPNC also shares the "Saint Thomas" name with the Saint Thomas Entities and is located in a building on the campus of St. Thomas Hospital. Plaintiffs note that STOPNC's patients had no notice

[19] "Apparent agency is essentially agency by estoppel; its creation and existence depend upon such conduct by the apparent principal as will preclude him from denying another's agency." White v. Methodist Hosp. S., 844 S.W.2d 642, 646 (Tenn. Ct. App. 1992). "Generally, to prove apparent agency, one must establish (1) the principal actually or negligently acquiesced in another party's exercise of authority; (2) the third person had knowledge of the facts and a good faith belief that the apparent agent possessed such authority; and (3) the third person relied on this apparent authority to his or her detriment." Mechs. Laundry Serv. v. Auto Glass Co. of Memphis, 98 S.W.3d 151, 157 (Tenn. Ct. 2002).

that St. Thomas Hospital was not the provider of care or that care provided by STOPNC was not subject to the control or supervision of St. Thomas Hospital. Moreover, once the fungal meningitis outbreak occurred, STOPNC instructed patients to report to St. Thomas Hospital emergency room for evaluation and treatment. Plaintiffs claim that they "relied on the reputation of St. Thomas Hospital when accepting medical care at [STOPNC]." See, e.g., Reed Compl. at ¶ 277.

These allegations are adequate to allege, if not actual agency, at least an apparent agency relationship between the Saint Thomas Entities and STOPNC, its physicians, nurses, and employees. See Boren ex rel. Boren v. Weeks, 251 S.W.3d 426, 432-37 (Tenn. 2008) (discussing apparent agency in a hospital context and finding agency where patients were not adequately informed that emergency-room physicians were not hospital employees). Under plaintiffs' allegations, taken as true, the Saint Thomas Entities held themselves out to the public as providing medical services and patients receiving care at STOPNC reasonably believed they were being treated by Saint Thomas employees. Plaintiffs' claims for vicarious liability against the Saint Thomas Entities under an agency theory are sufficiently pled.

Plaintiffs do not charge an agency relationship between STOPNC and the Ascension Parties, and fail to adequately allege agency between the Ascension Parties and the Saint Thomas Entities. There is no indication from the complaints that the Saint Thomas Entities were acting on behalf of the Ascension Parties or that patients believed the Saint Thomas Entities were agents of the Ascension Parties. The

Ascension Parties' motion to dismiss global claims is therefore allowed.

### 3. The Premier Defendants' Motion to Dismiss Global Claims (Docket # 831)

The Premier Defendants seek dismissal of various claims for failure to state a cause of action.

#### a. Negligence and Failure to Warn

The Premier Defendants contend that plaintiffs' claims for negligence, gross negligence, and failure to warn should be dismissed as subsumed by the New Jersey Products Liability Act ("NJPLA"), N.J.S.A 2A:58C-1, et seq. They argue that the NJPLA is the exclusive remedy for when an individual is harmed by a product, regardless of the legal theory supporting the case. The Premier Defendants note that while plaintiffs' claims are ostensibly rooted in negligence, they actually pertain to the safety of the medication (i.e., defendants were negligent in not ensuring a "safe" and "clean" product), and thus must be evaluated under the NJPLA. See, e.g., Port Authority of New York and New Jersey v. Arcadian Corp., 189 F.3d 305, 313 (3d Cir. 1999) ("Even though plaintiff alleges a negligence claim in Count I, this count is based solely on harm caused by defendants' allegedly defective products. It therefore falls within the [NJPLA], which is the 'sole basis under New Jersey law available to consumers injured by a defective product.'"). Because the NJPLA excludes providers of professional services as "sellers" under the act, the Premier Defendants conclude that plaintiffs cannot recover on their negligence claims.

Plaintiffs dispute that NJPLA has any application to their negligence and failure

to warn claims.[20] They argue that these claims are grounded in the Premier Defendants' negligent performance of their medical services in obtaining and administering the MPA, not in the defectiveness of the MPA itself. For example, the master complaint alleges that the Premier Defendants failed to exercise reasonable care to ensure that the drugs they purchased and administered to patients was manufactured in compliance with applicable pharmaceutical laws, and that they failed to perform the necessary due diligence to determine the safety and quality of NECC's drugs. See Master Compl. at ¶¶ 226-241. The complaint further alleges that the Premier Defendants failed to investigate whether NECC was a reputable and safe supplier of sterile injectable compounds and that they purchased such drugs in bulk from NECC without using patient-specific individual prescriptions as required by law. Id. Plaintiffs also fault the Premier Defendants for failing to properly inform patients about the "true nature" of the drug, NECC, and the risks and dangers associated with the MPA's administration. Id. at 301-302.

Plaintiffs contend that New Jersey law recognizes negligence and lack of informed consent as viable claims against health care providers for the negligent performance of their services even when a defective product may also be involved. In Snyder v Mekhjian, 582 A.2d 307 (N.J. Super. Ct. App. Div. 1990), a plaintiff who contracted AIDS as a result of receiving a contaminated blood transfusion during

[20] Plaintiffs did not bring separate products liability claims against the Premier Defendants and acknowledge that the NJPLA, unlike the TPLA, codified a common law rule that healthcare providers are generally not subject to strict liability claims based upon defective products tangentially used in connection with medical treatment. See N.J.S.A. 2A:58C-8 (term "product seller" does not include "[a] provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill or services.").

surgery brought strict liability and negligence claims against the physicians, hospital, and blood bank. He alleged that defendants failed to warn him of the risk of receiving contaminated blood and did not inform him of other options such as pre-banking his own blood or receiving donations from family members. He also alleged that the blood bank negligently failed to implement and follow risk-reducing screening procedures in the blood-collection process. The court allowed him to proceed on his negligence claims, even after granting summary judgment on his strict liability claims. Id. at 314 ("What we have said respecting strict liability does not, of course, affect plaintiffs' remaining negligence causes of action ... . [W]e have no doubt that the viability of the negligence cause of action against the physicians has been adequately demonstrated. ... [T]here is record support for the proposition that a jury could find that ... the physician's duty to inform the patient included advice as to the possibility of AIDS contamination and the availability of autologous and direct donor transfusion."). Similarly, in Johnson v. Mountainside Hosp., 571 A.2d 318, 321-22 (N.J. Super. Ct. App. Div. 1990), a wrongful death action involving a patient who died after being disconnected from a respirator, the court dismissed strict liability claims against the defendant hospital for a defective respirator, but permitted the plaintiff to bring negligence claims against the hospital and physicians in the performance of their services. See also New Jersey Courts, Model Civil Jury Charges, c. 5.40A, available at http://www.judiciary.state.nj.us/civil/charges/5.40A.pdf (noting that since the passage of the NJPLA, "there is one cause of action for recovery for harm caused by a product" but

that "[s]ome negligence actions involving products probably survive the Act.")

Plaintiffs have sufficiently stated claims for harm caused by alleged negligence by the Premier Defendants in obtaining and administering the contaminated MPA. These claims can be considered separate and viable on their own, regardless of whether defendants are exempt from strict liability under the NJPLA.

**b. Battery**

The parties' arguments as to plaintiffs' battery claims are essentially the same as those considered with the Tennessee Clinic Defendants. The Premier Defendants assert that plaintiffs have failed to allege that they did not consent to the injection – necessary to make out a claim for battery – and instead take issue with the lack of information given about the risks of NECC's compounded MPA, which is more appropriately characterized as an informed consent claim. Plaintiffs respond that they consented only to the injection of steroids into their bodies, not to "the injection of contaminated bacterial fungal and bacterial substances" nor to "the administration of mail-ordered medication from an unaccredited, non FDA approved compounding pharmacy they have never heard of, [that] was located hundreds of miles away and that their doctors and their practice had never visited or otherwise seen." Docket # 980 at 13.

Plaintiffs' position is untenable. They signed consent forms agreeing to the procedure (a steroid injection), which is exactly what they received. Plaintiffs' real grievance centers on the Premier Defendants' alleged failure to disclose certain

information about the nature of the MPA and risks of the procedure. "[T]he battery theory should be reserved for those instances where the patient consented to the performance of one kind of operation and the physician performed a substantially different one for which authorization was not obtained. ... That does not foreclose a plaintiff from claiming that the physician was negligent in failing to apprise the patient of the possible risk attendant to the operation. However he may not properly contend that the doctor committed an intentional tort, an assault and battery." Tonelli v. Khanna, 569 A.2d 282, 285-86 (N.J. Super. Ct. App. Div. 1990) (quoting Samoilov v. Raz, 536 A.2d 276 (App. Div. 1987)). Moreover, plaintiffs do not allege that the Premier Defendants injected the MPA with actual knowledge that it was contaminated.

Plaintiffs' battery claims against the Premier Defendants are dismissed for failure to state a claim.

**c. Civil Conspiracy**

As with the Tennessee Clinic Defendants, plaintiffs' civil conspiracy claims against the Premier Defendants do not adequately allege an underlying tort. See Banco Popular N. Am v. Gandi, 876 A.2d 253 (N.J. 2005) ("Most importantly, the gist of the claim is not the unlawful agreement, but the underlying wrong which, absent the conspiracy, would give a right of action."). Even if plaintiffs' allegations that the Premier Defendants conspired with NECC to violate Massachusetts pharmacy laws are true, it is unclear that such violations give rise to an actionable tort for plaintiffs. Plaintiffs also fail to allege facts regarding how the Premier Defendants conspired with

NECC, beyond generally stating that "upon information and belief the other Clinic Related Defendants had similar communications [as STOPNC, Dr. Culclasure, and Ms. Schamberg] with NECC." Master Compl. at ¶ 349. Plaintiffs' civil conspiracy claims are dismissed.

**d. Consumer Fraud**

Plaintiffs allege that the Premier Defendants' conduct constituted unfair or deceptive acts or trade practices in violation of the New Jersey Consumer Fraud Act ("NJCFA"), N.J.S.A. 56:8-1, et seq. Among other things, plaintiffs assert that the Premier Defendants represented to their patients that "the products administered had characteristics, uses and benefits that they did not have," "failed to provide accurate disclosures of all material information before Plaintiffs agreed to be injected with an NECC Contaminated Drug," "willfully and knowingly failed to abide by regulations, laws, and guidelines set forth to protect consumer safety," willfully and knowingly withheld important safety information, concealed the MPA's dangerous properties and risks, and represented their patients were receiving FDA-approved Depomedrol instead of NECC's compounded MPA. Master Compl. at ¶¶ 246-253.

The Premier Defendants argue that health care providers are specifically excluded from the NJCFA and thus those claims must be dismissed. They cite Macedo v. Dello Russo, 840 A.2d 238 (N.J. 2004), in which the plaintiff alleged that her physicians falsely represented that the doctors involved in her care were all fully licensed with no limitations on their licenses. The N.J. Supreme Court held that

"learned professionals" such as physicians were "beyond the reach of the [NJCFA] so long as they are operating in their professional capacities," including in advertising their services. Id. at 242. Plaintiffs counter that the learned professional exception does not apply because the Premier Defendants' misconduct here was not a matter of professional judgment or the quality of professional services related to patient treatment. Rather, plaintiffs contend that the crux of their NJCFA claims is that the Premier Defendants ordered and obtained for economic and convenience reasons, as opposed to medical reasons, compounded prescription drugs from NECC through illegally written prescriptions and then falsely passed off and billed the MPA as Depomedrol.

However, even in these alleged deceptive acts and practices, the Premier Defendants were not acting outside their professional capacities. The alleged conduct all took place in the context of providing health care. See DiCarlo v. St. Mary Hosp., 530 F.3d 255, 268 (dismissing plaintiff's NJCFA claim that defendant hospital's billing practices were unreasonable and unfair); Hampton Hosp. v. Bresan, 672 A.2d 725 (N.J. Super. Ct. App. Div. 1996) (granting summary judgment on patient's NJCFA claim against hospital alleging unlawful or unethical medical practices, implying the hospital kept him against his will for economic as opposed to medical reasons). The situation here is unlike other scenarios described in the case law as being "outside professional capacity." See, e.g., Macedo, 840 A.2d at 346 ("[I]f Dr. Dello Russo were to engage in the merchandising of a golf course, a vacation time-share or a medical office building,

he would be subject, as all merchandisers are, to the [NJ]CFA."); Blatterfein v. Larken, 732 A.2d 555 (N.J. Super. Ct. App. Div. 1999) (architect's activity as a real estate seller is subject to the NJCFA).

Accordingly, plaintiffs' NJCFA claims are dismissed.

**e. Agency**

Plaintiffs seek to hold the Premier Defendants vicariously liable for the conduct of NECC, alleging that NECC was acting as the Premier Defendants' agent. As with the Tennessee Clinic Defendants, plaintiffs claim that a consensual fiduciary relationship arose when the Premier Defendants contracted with NECC to procure compounded drugs from NECC for their patients, and that NECC consented to act as the Premier Defendants' agent, and in their interest, when compounding and delivering its drugs. See Master Compl., at ¶¶ 330-336. The master complaint also alleges that the Premier Defendants controlled the procurement of the drugs from NECC and that NECC acted within the scope of its agency when it negligently compounded drugs on behalf of the Premier Defendants. Id.

New Jersey law "recognizes a vicarious liability principle pursuant to which a master will be held liable in certain cases for the wrongful acts of his servants or employees." Carter v. Reynolds, 815 A.2d 460, 463 (N.J. 2003). In contrast, employers are ordinarily not liable for the negligent acts of independent contractors in the performance of a contract. Bahrle v. Exxon Corp., 678 A.2d 225, 231 (N.J. 1996). To establish liability, a plaintiff must prove "(1) that a master-servant relationship

existed and (2) that the tortious act of the servant occurred within the scope of that employment." Carter, 815 A.2d at 463. There are numerous factors used to determine whether agency exists, see Carter, id. at 464 (citing factors from Restatement (Second) of Agency, § 220), but the essential question is whether the employer exercised control over "both the nature of the work performed and the manner in which the work is completed," Lowe v. Zarghami, 731 A.2d 14, 19 (N.J. 1999). The court in Lowe applied a four-factor "control test" to determine a worker's status as either an employee or independent contractor: "(1) the degree of control exercised by the employer over the means of completing the work; (2) the source of the worker's compensation; (3) the source of the worker's equipment and resources; and (4) the employer's termination rights." Id. at 19-20.

The Premier Defendants contend that these factors do not favor plaintiffs' and have not been adequately alleged in the complaint. They maintain that they did not control the manner and means by which NECC performed its duties, including how NECC cleaned its laboratories and where it manufactured medication. The Premier Defendants acknowledge that they paid NECC for products and could have stopped ordering medications from NECC at any time, but note that they had no role in compensating or terminating NECC's employees. They also point out that they did not control or provide the equipment and resources used by NECC to manufacture MPA. Indeed, the complaint contains no allegations indicating that the Premier Defendants exercised any control over NECC or its conduct.

Plaintiffs nevertheless argue that even if a party is deemed to be an independent contractor as opposed to a servant or employee, a principal may still be held liable for the contractor's torts if it engages an incompetent contractor. Mavrikidis v. Petullo, 707 A.2d 977, 984 (N.J. 1998). Here, plaintiffs contend that they've sufficiently alleged that NECC "was incompetent or unskilled to perform the job for which [it] was hired" and that the Premier Defendants "knew or had reason to know of [NECC's] incompetence." Id. Plaintiffs point to allegations in the master complaint regarding the general risks of pharmacy compounding, NECC's non-FDA approved status, NECC's practice of selling large quantities of drugs wholesale, often without patient specific prescriptions, and the Premier Defendants' purported knowledge of all these things. See Master Compl. at ¶¶ 6, 48-53, 80-81, 159-162, 165-175, 178-182. However, as the Premier Defendants point out, plaintiffs do not allege that NECC was an *incompetent* independent contractor nor that the Premier Defendants were somehow aware of its incompetence.

Plaintiffs' claims for vicarious liability against the Premier Defendants are therefore dismissed.

**f. Punitive Damages**

Finally, the Premier Defendants argue that plaintiffs' claim for punitive damages must be dismissed. Under New Jersey's Punitive Damages Act:

> Punitive damages may be awarded to the plaintiff only if the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions. This burden of proof may not be satisfied by proof of any degree of negligence,

including gross negligence.

N.J.S.A. 2A:15-5.12. The Premier Defendants assert that while plaintiffs have alleged recklessness and gross negligence, they have not pled facts to support egregious, wanton, and willful conduct.

Plaintiffs, in contrast, insist that the master complaint is replete with factual allegations demonstrating that the Premier Defendants' conduct was willful and wanton, beyond mere negligence or gross negligence. Plaintiffs do make various assertions in the complaint that the Premier Defendants' actions "went beyond mere thoughtlessness, inadvertence or error of judgment," Master Compl. at ¶ 237, and "constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect for the safety of patients," id. at ¶ 239. They also allege that the Premier Defendants willfully and knowingly failed to abide by consumer safety regulations and withheld important safety information from patients. Id. at ¶ 249-50. Such allegations are enough to sustain plaintiffs' punitive damages claims at this early stage.

## IV. Conclusion

(1) The Tennessee Clinic Defendants' Motion to Dismiss for Failure to Comply with Tenn. Code. Ann. § 29-26-121 (Docket # 770) and the Saint Thomas Entities' and Ascension Parties' Motion to Dismiss for Failure to Comply with the Tennessee Health Care Liability Act (Docket # 779) are DENIED with respect to the limited questions presented by the parties.

As previously agreed by the parties, defendants may still seek dismissal based on other, case-specific issues relating to the THCLA.

(2) The Tennessee Clinic Defendants' Motion Dismiss Global Claims (Docket # 771) is ALLOWED IN PART and DENIED IN PART as follows:

(a) DENIED as to products liability claims.

(b) ALLOWED as to claims under the Tennessee Consumer Protection Act for recovery for personal injury or wrongful death, but DENIED as to such claims for the recovery of monies used to purchase MPA.

(c) ALLOWED as to battery claims.

(d) ALLOWED as to failure to warn (lack of informed consent claims) for defendants who did not order or administer injections, but DENIED as to all other defendants. Lack of informed consent claims will be evaluated under the THCLA.

(e) DENIED as to claims for ordinary negligence, gross negligence, and duty to prevent foreseeable harm, but such claims will be evaluated under the THCLA.

(f) ALLOWED as to civil conspiracy claims.

(g) ALLOWED as to vicarious liability claims.

(3) The Saint Thomas Entities' Motion to Dismiss Global Claims (Docket # 893) is DENIED. Plaintiffs' vicarious liability claims are insufficient under the alter ego theory, but adequately pled under an agency theory.

(4) The Ascension Parties' Motion to Dismiss Global Claims (Docket # 895) is ALLOWED.

(5) The Premier Defendants' Motion to Dismiss Global Claims (Docket # 831) is ALLOWED IN PART and DENIED IN PART as follows:

(a) DENIED as to claims for negligence and failure to warn.

(b) ALLOWED as to battery claims.

(c) ALLOWED as to civil conspiracy claims.

(d) ALLOWED as to claims under the New Jersey Consumer Fraud Act.

(e) ALLOWED as to agency claims (vicarious liability).

(f) DENIED as to punitive damages claims.

August 29, 2014
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE